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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,123	04/01/2004	Zheng Zhang	571-932	8039
1059 7590 12/28/2006 BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA			EXAMINER PENG, KUO LIANG	
			ART UNIT	PAPER NUMBER
			1712	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/28/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/814,123

Applicant(s)

ZHANG ET AL.

Examiner

Kuo-Liang Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/17/06 RCE.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39 and 62-73 is/are allowed.
- 6) ☒ Claim(s) 1-38, 40-61 and 74 is/are rejected.
- 7) ☒ Claim(s) 6-7, 11-36, 74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed October 17, 2006 has been entered. Claims 1, 38, 41, 49, 54 and 56-57 are amended. Now, Claims 1-74 are pending.

2. Applicants' should notice that the status identifiers of Claims 1, 39, 51, 55, 59, 62-63, 68 and 74 should be "Currently amended", "Previously presented", "Previously presented", "Previously presented", "Previously presented", "Previously presented" and "Previously presented", respectively.

3. It is noted that in Exhibit C (page 4) of the amendment filed October 17, 2006, "Sample 2 (DGS/**pH 5.5**/8% PEO10K)" should read -- Sample 2 (DGS/**pH 11**/8% PEO10K) -- as indicated in the picture of the vial label appears in the same page.

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4 The text of those sections of Title 35, U.S. code not included in this action can be found in prior Office Action(s).

Claim Objections

5. Claims 28-30 are objected to because of the following informalities:

In Claim 28 (line 5), should "lactose. dextran," be -- lactose, dextran --?

Appropriate correction is required.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-5, 8, 37-38, 40, 49-51, 54-60 and 74 are provisionally rejected

under the judicially created doctrine of obviousness-type double patenting as being

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unpatentable over Claims 25-27 and 37-40 of copending Application No. 10/449,511. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reason: Claims 25-27 and 37-40 of the copending Application are directed to methods of hydrolyzing an organic polyol silane in the presence of a hydrophilic polymer and methods of using the product obtained by the aforementioned methods, which obviously read on the methods set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-38, 40-61 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preparing siliceous materials at a pH in the range of **about** 4 to 11.5 (specification, page 16, last paragraph and Claim 38), does not reasonably provide enablement for a method of

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preparing siliceous materials at a pH in the range of **about 4 to about 11.5**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

10. Claims 1-5, 8-10, 37-38 and 40-56 rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhang ("The biporous structure of monolithic silica columns containing entrapped proteins" Abstract, submitted August 2002 Conference, published August 10, 2002).

For Claims 1-5, 8-10, 37-38, 41-47, 49 and 51-56, Zhang discloses a method of preparing silsiceous materials by hydrolyzing/condensing an **organic polyol silane precursor** with a **polyethylene oxide polymer**. The silsiceous materials are **macro and meso porous**. **Phase-separation** occurs during reaction. **Proteins** can be incorporated, in stable form for several months, into the silsiceous materials to create a **chromatographic** support. (Abstract) Zhang is silent on the specific claimed pH range. However, Zhang's method and the starting materials and the final product read on those of the instant claims. Examiner has a reasonable basis

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to believe that Zhang's method is carried out at the claimed pH. Especially, Applicants' declaration (**Exhibit C**) appears to show that with the starting materials at issue, it is critical to perform the reaction at the claimed pH in order to obtain the siliceous material containing **both macro and meso porosities**. The burden is thus shift to Applicants to show otherwise. If Applicants show that Zhang's pH is different from the claimed one, then, it is well known that the pH can affect, *inter alia*, the reaction rate and/or molecular weight of the resulting materials. In other words, the pH is a Result-Effective variable. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to carry out the reaction at whatever pH through routine experimentation in order to achieve a desired reaction rate and/or a material with proper molecular weight. See MPEP 2144.05 (II).

For Claims 40, 48 and 50, as mentioned above, in view of Applicants' Exhibit C, Zhang's siliceous material reads on the claimed material.

Claim Rejections - 35 USC § 103

11. Rejection of Claims 1-5, 8-10, 38, 40-45 and 47-48 under 35 USC 103(a) as being unpatentable over Nakanishi688 (US 5 009 688) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598), rejection of Claims 1-5, 8-10, 40-45, 47-52,

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54-55 and 56 under 35 USC 103(a) as being unpatentable over Nakanishi875 (US 5 624 875) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598), rejection of Claim 38 is under 35 USC 103(a) as being unpatentable over Nakanishi875 in view of Gill and as evidenced by Barkin (US 3 374 103) and rejection of Claims 53 and 57-61 under 35 USC 103(a) as being unpatentable over Nakanishi875 in view of Gill are maintained because the rejection is adequately set forth in paragraphs 5-8 of Paper No. 051306. Applicant's arguments have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below.

Applicants primarily argue that Exhibit C shows the unexpected results when the hydrolysis and condensation of the silane precursor is performed at the claimed pH. However, it is not persuasive because the SEM image of Sample 2 in Exhibit C appears not much different than those obtained from the samples using TEOS or PGS.

12. Claims 6-7, 11-36 and 74 would be allowable if rewritten to overcome double patenting rejection, claim rejection under 35 USC 112, first paragraph and/or claim objection, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

13. Claims 39 and 62-73 are allowed.

14. The following is an examiner's statement of reasons for allowance:

None of the above references, taken alone or in combination, teaches or fairly suggests the use of a compound of Formula I set forth in the present invention.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski, can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR

only. For more information about the PAIR system, see [http://pair-](http://pair-direct.uspto.gov)

[direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system,

contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

klp

December 23, 2006



Kuo-Liang Peng
Primary Examiner
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